

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/JP03/12781

## A. CLASSIFICATION OF SUBJECT MATTER

Int.Cl<sup>7</sup> A61K45/06, 9/20, 9/30, 31/155, 31/427, A61P3/10

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Int.Cl<sup>7</sup> A61K9/20-9/46, 31/155, 31/427, 45/00-45/08

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
CAPLUS (STN), MEDLINE (STN), WPI (DIALOG)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y A	WO 01/35941 A2 (SMITHKLINE BEECHAM P.L.C.), 25 May, 2001 (25.05.01), See especially, pages 14, 15 & AU 200114040 A & BR 200015605 A & NO 200202334 A & EP 1231918 A2 & SK 200200679 A3 & CZ 200201679 A3 & ZA 200203865 A & HU 200204122 A2 & CN 1414852 A & JP 2003-514012 A & KR 2003019300 A & NZ 518946 A	1-3, 7-12 4-6, 13, 14
Y	Written and edited by Sadashi OKANO, "Shin-Yakuzaigaku Soron (Kaitei Dai 3 Han)", Nankodo Co., Ltd., 10 April, 1987 (10.04.87), pages 155 to 160; particularly, page 155, lower part; page 157, lower part; page 159, lower part	1-3, 7-12

☒ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

\* Special categories of cited documents:  
"A" document defining the general state of the art which is not considered to be of particular relevance  
"E" earlier document but published on or after the international filing date  
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)  
"O" document referring to an oral disclosure, use, exhibition or other means  
"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention  
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone  
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art  
"&" document member of the same patent family

Date of the actual completion of the international search  
16 January, 2004 (16.01.04)Date of mailing of the international search report  
10 February, 2004 (10.02.04)Name and mailing address of the ISA/  
Japanese Patent Office

Authorized officer

Facsimile No.

Telephone No.

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## C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 02/30400 A1 (Takeda Chemical Industries, Ltd.), 18 April, 2002 (18.04.02), Particularly, page 25, lines 15 to 16 & AU 200194192 A & JP 2002-179558 A & EP 1329217 A1	1-3
A	WO 01/35940 A2 (SMITHKLINE BEECHAM P.L.C.), 25 May, 2001 (25.05.01), & AU 200114035 A & EP 1231917 A2 & JP 2003-514011 A	1-14
A	SUZUKI, Masami et al., Effects of combined pioglitazone and metformin on diabetes and obesity in Wistar fatty rats, Clinical and Experimental Pharmacology and Physiology, April 2002, Vol.29, No.4, pages 269 to 274	1-14

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## Box I Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:  
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:  
(See extra sheet.)

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest ☐ The additional search fees were accompanied by the applicant's protest.  
☐ No protest accompanied the payment of additional search fees.

Continuation of Box No. II of continuation of first sheet(1)

In claims, the matter common to (1) the inventions as set forth in claims 1 to 3; (2) the inventions as set forth in claims 4 to 6, 13 and 14; (3) the inventions as set forth in claims 7 to 9; and (4) the inventions as set forth in claims 10 to 12 resides in "improvement in uniformity in drug ingredient contents and preparation characteristics of a solid preparation containing an insulin resistance improving drug and an active ingredient (other than the insulin resistance improving drug)". However, "a solid preparation containing an insulin resistance improving drug and an active ingredient (other than the insulin resistance improving drug)" had been already publicly known before the filing of this international application (see, for example, WO 01/35941 A2 (SMITHKLINE BEECHAM P.L.C.) 2001.05.25) and improvement in uniformity in drug ingredient contents and solid characteristics is a problem which should be taken into consideration by those skilled in the art and was already well known at the filing of this international application. Thus, "improvement in uniformity of drug ingredient contents and preparation characteristics in a solid preparation containing an insulin resistance improving drug and an active ingredient (other than the insulin resistance improving drug)" cannot be regarded as "a special technical feature". That is, there is no "special technical feature" common to the invention groups (1) to (4) as described above.

Such being the case, the present claims have 4 groups of inventions (1) to (4) as described above which are different from each other.

## &lt;Subject of search&gt;

In claims, "an insulin resistance improving drug" and "an active ingredient" are presented as drug ingredients of the solid preparation. Since "an insulin resistance improving drug" and "an active ingredient" involve substances having various physical and chemical properties and the problem to be solved by the invention of the present international application closely relates to "improvement in uniformity in drug ingredient contents and preparation characteristics", i.e., the physical and chemical properties of the chemical ingredients, only parts of these ingredients are disclosed in the meaning within PCT Article 5 and sufficiently supported in the meaning within PCT Article 6.

Such being the case, the search was made on "pioglitazone and its salt" as the insulin resistance improving drug and "metformin and its salt" as the active ingredient.